

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION <hr/> THIS DOCUMENT RELATES TO: WAVE CASES ON ATTACHED EXHIBIT A	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**PLAINTIFFS' MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO
EXCLUDE THE GENERAL CAUSATION OPINIONS OF PETER JEPPSON, MD**

TABLE OF CONTENTS

INTRODUCTION.....	4
LEGAL STANDARD.....	4
I. THE COURT SHOULD EXCLUDE DR. JEPPSON’S OPINIONS REGARDING THE ADEQUACY OF RISK INFORMATION CONTAINED IN IFUs AND DEVICE LABELING BECAUSE HE IS NOT QUALIFIED TO RENDER SUCH OPINIONS.....	4
CONCLUSION.....	8

TABLE OF AUTHORITIES

<i>Huskey v. Ethicon, Inc.</i> , 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014).....	4
<i>Tyree v. Boston Scientific Corp.</i> , 54 F.Supp.3d 501 (S.D. W. Va.2014).....	6
<i>In re C.R. Bard, Inc.</i> , 948 F.Supp.2d 589, 611 (S.D.W.Va.2013).....	6
<i>Hoffman v. Monsanto Co.</i> , 2007 WL 2984692 (S.D.W.Va. Oct.11, 2007).....	8
<i>See Sanchez et al. v. Boston Scientific Corp.</i> , 2014 WL 4851989 (S.D.W.Va. Sept. 29, 2014)....	8

Plaintiffs submit this brief in support of their Motion to Exclude the General Causation Opinions of Peter Jeppson, M.D., as it relates to the cases set forth on Exhibit A to Plaintiffs' accompanying Motion.

INTRODUCTION

Dr. Jeppson is a urogynecologist in New Mexico with experience in the treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), as well as the removal of POP and sling systems. Dr. Jeppson intends to provide general opinions about: TVT, TVT-O, TVT-Abbrevio and abdominal Sacrocolpexy.¹ As discussed below, the Court should exclude certain opinions of Dr. Jeppson because: (1) he offers opinions on product warnings he is not qualified to offer; and (2) he offers regulatory opinions he is not qualified to offer. Because many of Dr. Jeppson's opinions are not the product of a reliable methodology and exceed his qualifications, certain of his testimony should be excluded.

LEGAL STANDARD

In addition to specific legal citations and argument contained in this Memorandum, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014).

I. THE COURT SHOULD EXCLUDE DR. JEPPELSON'S OPINIONS REGARDING THE ADEQUACY OF RISK INFORMATION CONTAINED IN IFUs AND DEVICE LABELING BECAUSE HE IS NOT QUALIFIED TO RENDER SUCH OPINIONS.

Dr. Jeppson offers numerous opinions regarding the adequacy of risks disclosed in IFUs that he is not qualified to render. Specifically, Dr. Jeppson states in his General Report that:

In my opinion, the TVT, TVT-O, and TVT-Abbrevio IFUs provided appropriate information for surgeons to be able to use the devices safely. They included information regarding the indications for use of the devices, contraindications, and

¹ See General Report of Peter Jeppson, MD, FACOG, FACS (attached as Exhibit B); General Sacrocolpexy Report of Peter Jeppson, MD, FACOG, FACS (attached as Exhibit C).

instructions on how to implant the devices. They also contained warnings and potential adverse reactions.

General Report, at p. 17. Dr. Jeppson continues, “In my opinion, the IFU does not need to contain information regarding risks that are not evidence-based, clinically significant or information on risks that are commonly known by gynecologists, urologists, or urogynecologists.” *Id.* at 17-18.

Dr. Jeppson’s General Sacrocolpexy Report similarly states:

In my opinion, the Prolene polypropylene mesh IFU and Gynemesh PS IFU provided appropriate information for surgeons to be able to use the meshes safely. They included information regarding the potential risks associated with the meshes and specific properties of the mesh.

General Sacrocolpexy Report, at p. 12.

The purported expert opinions that the risk information contained in these IFUs were “appropriate” are unreliable. Dr. Jeppson is not qualified to render expert opinions on the adequacy of risk information contained in an IFU or any other device labeling. Dr. Jeppson admits that he has no experience drafting an IFU for a product.² Nor has he ever designed a medical device.³ And he does not hold himself out as an expert in FDA regulations. Instead, in his own words, he “understand[s] the pelvis.”⁴ Being a urogynecologist who understands the pelvis does not qualify one to be an expert on the adequacy of IFU labeling, device warnings, or FDA compliance. Dr. Jeppson’s experience as a urogynecological surgeon, without more, does not qualify him to offer such expert testimony.

² Jeppson Depo (attached hereto as Exhibit D) at 111:13-15 (“Q. Have you ever written an IFU for a product? A. I have not written an IFU for a product.”).

³ *Id.* at 111: 16-19 (“Q. Have you ever designed a medical device? A. I’ve had discussions with people about medical devices. That’s not what I choose to do with my career.”).

⁴ *Id.* at 110:23-111:12 (“Q: Do you hold yourself out to be an expert in FDA regulations? A. So what I would say is I – as a urogynecologist, as a practicing surgeon and physician, I understand the pelvis. ... Am I – am a regulator? I am not.”).

Indeed, this Court was presented with similar expert testimony in *Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501 (S.D. W. Va.2014), and excluded such testimony. In *Tyree*, the plaintiff's expert, also a urogynecologist, sought to opine about BSC's alleged noncompliance with FDA regulations, including as they relate to product labeling. In excluding the expert, this Court said:

Without more, however, Dr. Ostergard's distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance. First, Dr. Ostergard admitted that he is "not an expert in FDA regulations. Second, his understanding of medical device warnings does not exceed the knowledge of physicians in general. That is, he has never drafted a device warning, and he only knows the "information that would be useful to the physician and his counseling of patients." This minimal experience with medical device warnings and FDA regulations does not satisfy the "knowledge, skill, experience, training, or education" required under Rule 702. *See, e.g., In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 611 (S.D.W.Va.2013) ("Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process.").

Id. at 551. Accordingly, this Court's precedent mandates the exclusion of any of Dr. Jeppson's opinions regarding the adequacy of the risk information contained in any mesh IFU, any device label, and FDA compliance.

The exclusion of Dr. Jeppson's labeling opinions are also appropriate because they are unreliable. When confronted at his deposition with internal company documents regarding the risks that Ethicon knew about its mesh products before the products were launched to market—risks that were not conveyed to physicians—Dr. Jeppson admitted that he did not know what Ethicon did or did not know about the risks associated with their mesh devices prior to launch.⁵

⁵ Q. Doctor, do you understand or know that Ethicon knew of the risks and adverse reactions we've gone through regarding the TVT-O before the time the TVT-O was launched?

MR. KOOPMANN: Objection.

For instance, in support for his statement that the warnings contained in the various IFUs were “appropriate,” Dr. Jeppson states that “the IFUs for the TVT-O and TVT-Abbrevio also warned of possible transient leg pain lasting 24-48 hours.”⁶ However, at his deposition, Dr. Jeppson did not know whether the IFU for the TVT-O included a risk of groin pain or leg pain when it came on the market.⁷

Simply put, in rendering his labeling opinions, Dr. Jeppson did not consider what Ethicon knew of the potential risks of its mesh devices or when they knew it. Knowing when risks become known is a hallmark of assessing whether any disclosure of those risks was first, timely, and second, adequate. For Dr. Jeppson to not consider this information in forming his opinions regarding the adequacy of the IFUs renders those labeling opinions wholly uninformed. Without a reliable foundation, Dr. Jeppson’s labeling opinions are unreliable. *See, e.g., Hoffman v.*

A. You know, again, I've seen some internal documents from Ethicon. I do not remember everything. I'd have to go back and look and I don't pretend to know everything Ethicon did or didn't know at the time.

BY MR. BRADFORD: Q. Doctor, do you agree that Ethicon knew of all the risks regarding the TVT Abbrevio we just went through before the time of launch?

MR. KOOPMANN: Objection.

A. You know, again, I don't know what they did or didn't know.

Jeppson Depo, at 147:6-22.

⁶ General Report, at p. 17.

⁷ Q. Do you know whether or not the IFU for the TVT-O, when it came on the market, described the risk of groin pain or leg pain?

A. I've looked at the IFUs. I looked at an earlier version and a more updated version, but I don't recall offhand. I'd have to go back and look.

Id. at 177:20-178:1.

Monsanto Co., 2007 WL 2984692, at *3–5 (S.D.W.Va. Oct.11, 2007) (Goodwin, J.) (excluding opinions of a “very qualified” expert because the basis for the testimony was unreliable).

Moreover, Dr. Jeppson claims to be an expert on TVT, TVT-O, and TVT-Abbrevio.⁸ In that role, he intends to talk to the jury about the safety and efficacy of these devices from their inception to the present.⁹ Yet, Dr. Jeppson was unable to recall the predicate device upon which these devices were based. He admits that he did not review these basic regulatory facts in preparation for his opinions in this case.¹⁰

Q. Do you know what the predicate device was for the TVT?

A. I've heard. I don't -- I don't remember off the top of my head. I know I read it as a -- as a fellow and probably as a resident. I didn't review it again for this.¹¹

Dr. Jeppson's failure to review the basic foundational information upon which he intends to provide “expert” testimony casts serious doubt on whether these opinions would be helpful to the jury. *See Sanchez et al. v. Boston Scientific Corp.*, 2014 WL 4851989, at *35 (S.D.W.Va. Sept. 29, 2014) (“Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations.”). Because Dr. Jeppson lacks any real understanding of the regulatory history, labeling history, or internal company knowledge relating to potential risks with respect to the very mesh devices he purports to be “expert” in, his testimony regarding these issues are unreliable and should be excluded.

⁸ *Id.* at 167:14-167:5.

⁹ *Id.*

¹⁰ *Id.* at 166:17-22.

¹¹ *Id.* at 166:17-22.

CONCLUSION

Dr. Jeppson's reports are not well grounded in reliable methodology. He offers labeling opinions regarding IFUs even though he has no experience drafting IFUs. He offers opinions with respect to the appropriateness of labeling when he has no background knowledge or discernable understanding of the products regulatory history or what information Ethicon had in its possession regarding risks, much less when Ethicon acquired that information. Accordingly, his labeling opinions lack foundation, are inherently unreliable, and should be excluded.

Dated: June 3, 2019

Respectfully submitted,

/s/ Bryan F. Aylstock

Bryan F. Aylstock, Esq.

Aylstock, Witkin, Kreis and Overholtz, PLC

17 East Main Street, Suite 200

Pensacola, Florida 32502

(850) 202-1010

(850) 916-7449 (fax)

baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on June 3, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32502
(850) 202-1010
(850) 916-7449 (fax)
baylstock@awkolaw.com